

**REMARKS/ARGUMENTS**

The amendments to claims 7 and 12 are supported in the specification on page 6, line 19 and page 5, lines 4-5. These amendments do not add new matter to the specification and their entry is requested.

Claims 7-11, and 12-15 has been provisionally rejected under 35 U.S.C. section 101 as allegedly duplicative of claims 9-13 and 15-18 of U.S. Patent Application 11/054,742. Solely in an effort to expedite prosecution, Applicants have amended the claims to recite the administration of dehydroepiandrosterone or dehydroepiandrosterone sulfate. Since these two compounds are not recited in claims 9-13 and 15-18 of U.S. Patent Application 11/054,742, the claims as amended are not duplicative and the withdrawal of this rejection is respectfully requested.

The Office Action also alleged that claims 14 and 15 were duplicative. While Applicants disagree, claim 15 has been canceled and this issue is moot.

Claims 7 and 12 stand rejected under the judicially created doctrine of non-statutory obviousness-type double patenting as allegedly duplicative of claim 1 of U.S. patent 6,565,851. Solely in an effort to expedite prosecution, Applicants have amended claims 7 and 12 to recite the administration of dehydroepiandrosterone or dehydroepiandrosterone sulfate. Since these two compounds are not recited in claim 1 of U.S. patent 6,565,851, the claims as amended are not duplicative and the withdrawal of this rejection is respectfully requested.

Claims 7-15 stand provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 9-13 and 15-18 of U.S. Patent Application 11/054,742. Solely in an effort to expedite prosecution, Applicants have amended the claims to recite the administration of dehydroepiandrosterone or dehydroepiandrosterone sulfate. Since these two compounds are not recited in claims 9-13 and 15-18 of U.S. Patent Application 11/054,742, withdrawal of this rejection is respectfully requested.

Claims 7-8 and 12-13 stand rejected under 35 U.S.C. section 102 as allegedly anticipated by international application publication number WO 00/00212 (referred to herein as "Shell").

Applicants respectfully traverse. Solely in an effort to expedite prosecution, Applicants have amended the claims 7 and 12 to recite the administration of dehydroepiandrosterone or dehydroepiandrosterone sulfate. Since these compounds are not disclosed by the Shell, claims 7 and 12 and claims dependent thereof (claims 8 and 13) cannot be anticipated. The withdrawal of this rejection is respectfully requested.

Claims 9-11 and 14 and 15 stand rejected under 35 U.S.C. section 103 as allegedly obvious in view of the Shell and U.S. Patent 5,906,987 (referred to herein as Chwalisz). Applicants traverse.

The claimed invention, as amended, is directed to the administration of dehydroepiandrosterone or dehydroepiandrosterone sulfate along with a source of arginine and proanthocyanidins to attain an enhanced level of sexual wellness of both sexes. This is not taught or suggested by Shell or Chwalisz.

Shell refers to the use of NO and NO agonist for treating erectile dysfunction. Unlike Applicants' claimed invention, Shell does not disclose or suggest the administration of dehydroepiandrosterone or dehydroepiandrosterone. In fact, Shell does not claim or suggest that proanthocyanidins in combination a source of arginine and dehydroepiandrosterone or dehydroepiandrosterone would be useful for promoting sexual wellness in both sexes. For this reason, Shell does not render the claimed invention obvious. The addition of Chwalisz does not cure this defect.

There is no motivation to combine Shell with Chwalisz because Chwalisz is directed to treating climacterium in male mammals only (see, e.g., the abstract, summary of invention, and claims of Chwalisz). Chwalisz refers to the administration of a NO substrate and androgen for treatment of a male mammal wherein "the circulating levels of testosterone" in the afflicted individual are increased (See, Chwalisz, abstract). There is no motivation to combine Shell, and Chwalisz to derive a method of treatment for both sexes, as recited in the instant claims, because an increase in testosterone level is considered by many females to be undesirable. In fact, the disclosure of Chwalisz, that its method can increase testosterone levels, teaches against using the combination for the treatment of both sexes - as recited by Applicants' claims.

Furthermore, even if Shell and Chwalisz were combined, it would not lead to Applicants' claimed invention. Neither Shell nor Chwalisz disclose or suggest the use of dehydroepiandrosterone or dehydroepiandrosterone sulfate, a recitation of the instant claims. Since a combination of the references does not lead to each and every recitation of the claimed invention, the instant claims cannot be obvious in view of a combination of Shell and Chwalisz.

For the reasons stated above, Applicants assert that the claimed invention is not obvious in view of Shell and Chwalisz and the withdrawal of the rejection of claims 9-11 and 14 and 15 under 35 U.S.C. section 103 is respectfully requested.

### CONCLUSION

Favorable action on the merits is respectfully requested. If any discussion regarding this Amendment is desired, the Examiner is respectfully urged to contact the undersigned at the number given below, and is assured of full cooperation in progressing the application to allowance.

Applicants believe that no additional fees are due with the filing of this Response. However, if any additional fees are required or if any funds are due, the USPTO is authorized to charge or credit Deposit Account Number: **50-0311**, Customer Number: **35437**, Reference Number **27990-504**.

Respectfully submitted,

  
Eric Sinn

Dated: July 26, 2006

Marvin S. Gittes, 24,350  
Eric Sinn, Reg. No. 40,177  
Attorneys for Applicants  
MINTZ, LEVIN, COHN, FERRIS, et al.  
666 Third Avenue, 24<sup>th</sup> Floor  
New York, NY 10017  
Phone: (212) 935-3000  
Fax: (212) 983-3115